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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/242,657      | 02/19/1999  | PETER RUHDAL JENSEN  | 55411.000002        | 1335             |

21967 7590 06/29/2005

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EXAMINER

MCGILLEM, LAURA L

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1636

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/242,657 | <b>Applicant(s)</b><br>JENSEN ET AL. |  |
|                              | <b>Examiner</b><br>Laura McGillem    | <b>Art Unit</b><br>1636              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04/12/05.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 6-11, 13-18, 21-23, 25 and 27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16-17 and 22 is/are allowed.
- 6) ☐ Claim(s) 1-4, 6-11, 13-15, 21, 23, 25 and 27 is/are rejected.
- 7) ☐ Claim(s) 18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/19/1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date: _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____  | 6) <input type="checkbox"/> Other: _____                                    |

*jl*

### DETAILED ACTION

In the amendment filed 4/12/2005, several claims were amended (Claims 1, 3, 4, 14, 16, 17, 18 and 21). Claims 1-4, 6-11, 13-18, 21-23, 25 and 27 are pending and are under consideration.

The following is a quotation of the first paragraph of 35 U.S.C. 112 that form the basis for the rejections under this section made in this Office action:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-11, 13-15, 21, 23, 25 and 27 are rejected under 35 U.S.C. 112, first paragraph as containing subject matter which was not described in the specification in such as way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed, had possession of the claimed invention.

The rejection is maintained for reasons of record in the previous Office action (mailed 8/10/04) and for reasons outlined below.

Applicants traverse this rejection by amending the claims to include a Markush group of the specific microorganisms from the examples in the application (for example, claim 1 recites "a microorganism selected from the group consisting of lactic acid bacteria, *Bacillus*, *E. coli*, *Pseudomonas* and yeast").

Applicants argue that the claims specifically recite structural characteristics of the promoter sequences and functional characteristics of the promoter activities and that

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this is coupled with a "disclosed correlation between function and structure. Thus, the Applicants respond that there is more than adequate basis for one skilled in the art to envision the claimed promoter sets.

Applicants' arguments to rejection of claims under 35 U.S.C.112, first paragraph filed in the response of 4/12/2005 have been fully considered but they are not persuasive.

Applicants have not provided sufficient structural/functional basis for one of skill in the art to envision those promoter sets that retain the conserved sequences and also satisfy the functional limitations of the claim with regard to step-wise increments in promoter activity among the members of the promoter set for the incredibly broad genus of such promoter sets encompassed by the rejected claims (i.e. literally any combination of activity range, gene and organism, or combination of organisms).

The written description requirement may be satisfied by a sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure or by a combination of such identifying characteristics, sufficient to show that applicant was in possession of the claimed invention. In the present case, applicants have not presented a correlation between promoter sets that retain the conserved sequences that change promoter activity in step-wise increments of change in promoter activity. Without elucidation of the sequences which are essential for a promoter to optimize the expression of gene by changing promoter

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activity in stepwise increments, the skilled artisan would not be able to recognize whether any given set of conserved promoter sequence would or would not be suitable for optimizing the expression of a gene in the manner described above. It must be considered, absent evidence to the contrary, that the representative number of species is not sufficient to provide a description of the claimed genus. Therefore, one of skill in the art would not have been able to envision a representative number of specific promoter sets to describe the broad genus of promoter sets encompassed by the rejected claims. One of skill in the art would thus have reasonably concluded applicants were not in possession of the claimed invention for claims 1-4, 6-11, 13-15, 21, 23, 25 and 27.

The following is a quotation of the second paragraph of 35 U.S.C. 112 that form the basis for the rejections under this section made in this Office action:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-11, 13-18, 21, 23, 25 and 27 were rejected as unclear because they recite the phrase “an activator binding site upstream” or “a UAS upstream of”.

Applicants traverse this rejection by amending the claims to include the phrases “at least one of” and “at least one of said at least two consensus sequences is”.

Rejection of claims 1-4, 6-11, 13-18, 21, 23, 25 and 27 under 35 U.S.C. 112, second paragraph is withdrawn.

Claim 21 is rejected as vague and indefinite because the metes and bounds of the term "pathway" is unclear regarding what type of pathway is proposed and that there is no antecedent basis for the term "cellular metabolite" or "the clone".

Applicants traverse the rejection of claim 21 by amending claim 21 to include the phrase "pathway of the cellular metabolism" and also "a cellular metabolite" and "clone selected in step [sic]".

Applicant's arguments filed 4/12/2005 have been fully considered but they are not persuasive because claim 21 does not define which pathway of the cellular metabolism is intended. The "clone" in part (iv) continues to lack clear and positive antecedent basis since the step in which the clone is selected is not specified.

### ***Claim Objections***

Claim 18 is objected to because of the following informalities: the word microorganism is misspelled in the first line of section b). Appropriate correction is required.

Claim 1 is objected to because of the following informalities: the amendment to section b) in which the phrase "being selected from the group consisting of" has been removed has rendered the sentence grammatically incorrect because no verb has been added in place of the removed phrase. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

Claims 14 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **These are new rejections necessitated by amendment filed 4/12/2005.**

Claim 14 recites the phrase "derived from" in the context of a 199 base pair nucleotide sequence which include wild card bases (SEQ ID NO:3) making unclear the nature and number of steps required in order to obtain a "derivative" of the oligonucleotide. Examiner suggests replacing the phrase "derived from" with the phrase "obtained from". The phrase "derived from" implies an indirect process, while the phrase "obtained from", implies a more direct process for obtaining the desired products.

Claim 21 is vague and indefinite in that the selection step recited in part (iv) is not sufficiently identified.

**Conclusion**

Claims 16-17 and 22 are allowed. Claims 1-4, 6-11, 13-15, 21, 23, 25 and 27 are rejected.

Claim 18 is objected to.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura McGillem whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should



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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura McGillem  
6/27/05

  
DAVID GUZO  
PRIMARY EXAMINER